



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2009-0681; FRL-9332-4]

Final Test Guidelines; OCSPP 810 Series; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the availability of the final test guidelines for Series 810--Product Performance Test Guidelines, specifically public health uses of antimicrobial agents (OCSPP 810.2000), sterilants (OCSPP 810.2100), disinfectants (OCSPP 810.2200), and sanitizers (OCSPP 810.2300). These test guidelines are part of a series of test guidelines established by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in testing pesticides and chemical substances to develop data for submission to the Agency under the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and section 408 of the Federal Food, Drug and Cosmetic (FFDCA). As guidance documents, the test guidelines are not binding on either EPA or any outside parties.

FOR FURTHER INFORMATION CONTACT: *For general information contact:*

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For technical information contact: Michele E. Wingfield, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6349; email address: *wingfield.michele@epa.gov*.

FIFRA information contact: Communications Services Branch (7506P), Field and External Affairs Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5017; fax number: (703) 305-5558.

SUPPLEMENTARY INFORMATION:

I. Introduction

These test guidelines are part of a series of test guidelines established by OCSPP for use in testing pesticides and chemical substances to develop data for submission to the Agency under TSCA (15 U.S.C. 2601 *et seq.*), FIFRA (7 U.S.C. 136 *et seq.*), and section 408 of the FFDCA (21 U.S.C. 346a).

The test guidelines serve as a compendium of accepted scientific methodologies and protocols that are intended to provide data to inform regulatory decisions under TSCA, FIFRA, and/or FFDCA. The test guidelines provide guidance for conducting the test, and are also used by EPA, the public, and the companies that are subject to data submission requirements under TSCA, FIFRA, and/or FFDCA.

II. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under TSCA, FFDCA, and/or FIFRA, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any

questions regarding the applicability of this action to a particular entity, consult the appropriate person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket for this document.* EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0681. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

2. *Electronic access to OCSPP test guidelines.* To access OCSPP test guidelines electronically, please go to <http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm>. You may also access the test guidelines in <http://www.regulations.gov>, grouped by series under docket ID numbers: EPA-HQ-OPPT-2009-0150 through EPA-HQ-OPPT-2009-0159 and EPA-HQ-OPPT-2009-0576.

III. What Action is EPA Taking?

EPA is announcing the availability of the final test guidelines for Group B--Product Performance Test Guidelines for Public Health Uses of Antimicrobial Agents in OCSPP Series 810--Product Performance Test Guidelines:

1. General Considerations for Public Health Uses of Antimicrobial Agents (OCSPP 810.2000).
2. Sterilants--Efficacy Data Recommendations (OCSPP 810.2100).

3. Disinfectants for Use on Hard Surfaces--Efficacy Data Recommendations (OCSPP Guideline 810.2200).

4. Sanitizers for Use on Hard Surfaces--Efficacy Data Recommendations (OCSPP 810.2300).

These final test guidelines address efficacy testing for antimicrobial agents intended to be used on hard, inanimate, environmental surfaces and which bear label claims as sterilants, disinfectants, and sanitizers.

As guidance documents, the test guidelines are not binding on either EPA or any outside parties, and EPA may depart from the test guidelines where circumstances warrant and without prior notice. At places in this guidance, the Agency uses the word “should.” In this guidance, use of “should” with regard to an action means that the action is recommended rather than mandatory. The procedures contained in the test guidelines are recommended for generating the data that are the subject of the test guideline, but EPA recognizes that departures may be appropriate in specific situations. Alternatives to the recommendations described in the test guidelines may be proposed, and the Agency will assess them for appropriateness on a case-by-case basis.

IV. How Were These Test Guidelines Developed?

The product performance guidelines for antimicrobial agents were last updated in 1982 under the “Pesticide Assessment Guidelines – Subdivision G, Product Performance.” Since then, the Agency has presented several issues at two separate meetings of the FIFRA Scientific Advisory Panel (SAP) related to the conduct of studies for antimicrobial agents (the first meeting September 9-10, 1997, announced in the **Federal Register** issue of July 14, 1997 (62 FR 37584) (FRL-5731-4) and the second

meeting July 17-19, 2007, announced in the **Federal Register** issue of March 14, 2007 (72 FR 11867) (FRL-8118-7). Information and recommendations regarding these two FIFRA SAPs can be found at the Office of Science and Coordination and Policy's website at <http://www.epa.gov/scipoly/sap/index.htm>. The test guidelines were also published for comment in the **Federal Register** issue of January 2010 (75 FR 4380) (FRL-8437-2) and revised based on comments received from industry. In addition to formatting changes to incorporate the test guidelines into the OCSPP 810 Series, EPA has added sections that incorporate new guidelines and clarifications from other guidance documents. In particular, data recommendations for testing against the spore formers *Bacillus anthracis* and *Clostridium difficile* have been added.

List of Subjects

Environmental protection, Antimicrobials, Chemical testing, Test guideline.

Dated: March 5, 2012.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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